



NDA 50-441/S-047

Pharmacia & Upjohn Company
Attention: Rebecca Tong, MS
7000 Portage Road
Kalamazoo, MI 49001-0199

21 NOV 2001

Dear Ms. Tong:

Please refer to your supplemental new drug application dated October 4, 2001, received October 5, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cleocin Phosphate® (clindamycin injection, USP) sterile solution. We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This supplemental new drug application provides for revised container (vial) labels and cartons for the product.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (immediate container and carton labels submitted October 4, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Beth Duvall-Miller, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely,

Janice M. Soreth, M.D.
Acting Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research